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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/586,768

07/20/2006

Andreas Meudt

2004DE302

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11/05/2008

PROPAT, L.L.C.

425-C SOUTH SHARON AMITY ROAD

CHARLOTTE, NC 28211-2841

EXAMINER

MABRY, JOHN

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

11/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/586,768 | <b>Applicant(s)</b><br>MEUDT ET AL. |  |
|                              | <b>Examiner</b><br>John Mabry, PhD   | <b>Art Unit</b><br>1625             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination (RCE)***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 5, 2008 has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no evidence/written description in the specification for R of Formulas II and III for the terms "substitution, alkyl, alkenyl, alkynyl and cycloalkyl". Additionally, there are no examples or reduction to practice of said groups.

According to the MPEP §2163 I. A. “the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.” The MPEP states in §2163 II 3 ii) “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43, USPQ2d at 1406.”

As discussed above the phrase “substitution, alkyl, alkenyl, alkynyl and cycloalkyl” is not art recognized in the specification. According to the MPEP §2163.02 Standard for Determining Compliance With the Written Description Requirement,

“The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed”. *In re Gosteli*, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed.

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The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter”. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983)).”

The methodology for determining adequacy of written description to convey that Applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (Guidelines for Examination of Patent Applications under 35 USC § 112, p 1 "Written Description" Requirement; (Federal Register/Vol 66. No. 4, Friday, January 5, 2001;11 Methodology for Determining Adequacy of Written Description (3.)).

### ***Claim Coverage***

The instant application claims a process for preparing a) nitriles of the formula II and b) isonitriles of the formula III.

### ***Applicants' Reduction to Practice***

According to the Specification at the time of filing, Examiner has concluded that Applicant was not in possession of the claimed invention.

*Level of Skill and Knowledge in the Art*

The ordinary artisan is highly skilled, e.g. a masters or PhD in the chemical sciences. The level of skill in the art is high because of experimentation may be expansive and unpredictable.

According to the MPEP §2163 I. A. “the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has been described with sufficient particularity such that one skilled in the art would recognize that eh applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the area or known to one of ordinary skill in the art.” The MPEP states in §2163 II 3 ii) “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see I) (A), above), reduction to drawings (see I)(B), above), or by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see I)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43, USPQ2d at 1406.”

As discussed above, the R groups being “akyl, alkenyl, alkynyl and cycloalkyl and the term substitution” is not defined or contained in the Specific and the art recognized definitions are shown to be inconsistent.

According to the MPEP §2163.02 Standard for Determining Compliance with the Written Description Requirement,

“The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed”. *In re Gosteli*, 872, F.2d 1008 1012, 10 USPQ2d 1614, 1618 (Fed. Cir.1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter”. *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 217 USPQ 1089, 1096 (Fed. Cir. 1983)).”

#### *Working Examples and Guidance Provided*

The Specification does not demonstrate any support for R being anything

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chemical moiety other than phenyl, methylphenyl and methyl 3-phenylpropanoate.

There are no working examples of claimed process wherein any “substitution, alkyl, alkenyl, alkynyl and cycloalkyl” is used. The Specification does not even meet the minimum art recognized experimental standards. In the art, the claimed process of preparing only uses phenyl, methylphenyl and methyl 3-phenylpropanoate groups. However, there are no examples using art recognized where R is any chemical moiety other than phenyl, methylphenyl and methyl 3-phenylpropanoate in the instant applicant. There is no data is provided in the Specification that teaches the full claimed scope of how to make the products II and III.

#### *State of the Art and Analysis of the Issues*

The nature of the invention is the process of preparing compounds II and III where R is all aryl and heteroaryl groups (which is not defined in the Specification); the state of the prior art is not well developed and is highly unpredictable. There are no teachings of how to make the claimed compounds where R is “alkyl, alkenyl, alkynyl and cycloalkyl with any substitution”. This is merely an unsubstantiated assertion with no evidence to support. With the lack of examples and guidance as discussed above, one of ordinary skill in the art would reasonably have considered that at the time the application was filed, that the Applicant was not in possession of the claimed invention.

#### **Conclusion**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for



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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's primary examiner can be reached at (571) 272-0684, first, or the Examiner's supervisor, Janet Andres, PhD, can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/John Mabry/  
Examiner  
Art Unit 1625

/Rita J. Desai/  
Primary Examiner, Art Unit 1625